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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,550	11/13/2001	Geeta Saxena	SMAR-017CIP	1457

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	5

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/992,550	Applicant(s) SAXENA ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 4, 7, and 23-37, drawn to a method of treating a chemokine mediated disease state, classified in class 514, subclass 468, 569, 577, 656, 532, and 556.

II. Claims 2-3, 5-6, drawn to a method of modulating the activity of a chemokine or chemokine receptor in host, classified in class 514, subclass 468, 569, 577, 656, 532, and 556.

III. Claims 8-22, drawn to a pharmaceutical composition, classified in class 424, subclass 400+.

IV. Claim 38, a method of treating a disease, classified in class 514, subclass 468, 569, 577, 656, 532, and 556.

The inventions are distinct, each from the other because of the following reasons:

Inventions III and I, II, IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating the diseases can be practiced with a materially different products such as

NSAID for arthritis, Steroid for inflammatory bowel diseases; chemotherapy agents for various carcinoma and so on.

Inventions I, II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The invention of Group I functions to treat a chemokine mediated disease state; the invention of Group II functions to modulate the activity of a chemokine or chemokine receptor in host; the invention of Group IV functions to treat a disease.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

Claims 1-38 are generic to a plurality of disclosed patentably distinct species comprising an active agent which is represented by compound of Formula I-XV.

Some of these include, for example, if the compound is of Formula II, it is classified in class 514, subclass 468; if the compound is of Formula III, it is classified in class 514, subclass 569; if the compound is of Formula IV, it is classified in class 514, subclass 577; if the compound is of Formula V, it is classified in class 514, subclass 656; if the compound is of Formula VI, it is classified in class 514, subclass 532; if the compound is of Formula XV, it is classified in class 514, subclass 556.

Due to the structural dissimilarities of active compounds encompassed by the claims and their corresponding diversity in classification, the search for all species presents an undue burden on the office.

Moreover, claims 1-7 and 23-38 are generic to a plurality of disclosed patentably distinct species comprising various disease states. The species are, for example, asthma, arthritis, carcinoma, and HIV infection. The method of treating each of these disease states are patentably distinct from each other because these disease states are routinely treated with different modalities and/or agents, which they cannot be used interchangeably. For example, arthritis is routinely treated with COX-2 inhibitors or Non-Steroidal Anti-inflammatory agents, which are not useful for treating asthma or HIV infection or asthma; asthma is routinely treated with β_2-agonists, which are not useful treating carcinoma or HIV infection; carcinoma are routinely treated with cytotoxic agents, which are not useful in treating depression or inflammation or HIV infection.

Due to the different distinct disease states encompassed by the claims and the different medical technologies associated thereto, the search for all species presents an undue burden on the office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed active agent compound if the invention of Group III is elected, even though this requirement is traversed. In addition, Applicant is required under 35 U.S.C. 121 to elect a single disclosed active agent compound **and** a single disclosed disorder if the invention of Group I, II, or IV is elected, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell Travers, J.D., can be reached on (703) 308-4603. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
July 27, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200